AMENDED IN ASSEMBLY APRIL 23, 2015

AMENDED IN ASSEMBLY MARCH 23, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 940

Introduced by Assembly Members Ridley-Thomas and Waldron

February 26, 2015

An act to amend Sections *1203,* 1204, 1205, 1206, 1207, 1209, 1210, 1260, 1261.5, 1264, and 1300 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 940, as amended, Ridley-Thomas. Clinical laboratories.

Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Existing law prohibits the performance of a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) unless the test or examination is performed under the overall operation and administration of a laboratory director. Existing law defines "laboratory director," for purposes of a clinical laboratory test or examination classified as waived, as any person who, among others, is licensed to direct a clinical laboratory and who substantially meets the laboratory director qualifications under the CLIA.

This bill would delete the requirement that a laboratory director substantially meet the laboratory director qualifications under CLIA. The bill would instead limit the CLIA qualification requirements to a person serving as the CLIA laboratory director, as defined, in a laboratory that performs tests classified as moderate or high complexity.

Existing law authorizes a person licensed as a clinical laboratory bioanalyst or bioanalyst and qualified under CLIA, and other persons licensed in specified clinical specialties, to perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, within the area of the licensee's specialty.

This bill would specify that this authorization extends to a person who is not the CLIA laboratory director under specified circumstances.

Existing law defines a "clinical laboratory scientist" as any person, other than a licensed clinical laboratory bioanalyst or trainee, who is licensed, as specified, to engage in a clinical laboratory practice under the overall operation and administration of a laboratory director.

The bill would add "reproductive biology" to the list of specialties that a clinical laboratory scientist may perform. The bill would make conforming changes.

Existing law requires an applicant for a clinical laboratory bioanalyst's license to meet specified requirements for education and experience, including that the applicant have a minimum of 4 years' experience as a licensed clinical laboratory scientist performing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory approved by the State Department of Public Health.

This bill would revise the application requirements to provide that an applicant's minimum of 4 years' experience be in a clinical laboratory certified under the CLIA.

Existing law authorizes the State Department of Public Health to issue specified licenses, including limited clinical laboratory scientist licenses and clinical licenses in specified fields, and establishes application and annual renewal fees for the clinical licenses. Existing law deposits those fees in the Clinical Laboratory Improvement Fund for use, upon appropriation by the Legislature, for regulatory purposes relating to clinical laboratories, blood banks, or clinical laboratory personnel, as provided.

This bill would authorize the department to issue limited clinical laboratory scientist licenses and clinical licenses in reproductive biology and biochemical genetics, as provided, and would apply existing application and license renewal fees to persons applying for additional clinical licenses.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1203 of the Business and Professions Code is amended to read:

1203. As used in this chapter, "clinical laboratory bioanalyst" or "bioanalyst" means a person licensed under Section 1260 to engage in clinical laboratory practice and direction of a clinical laboratory. ~~A~~

(a) A person licensed as a clinical laboratory bioanalyst or bioanalyst and qualified under ~~CLIA~~ *CLIA, who is not the CLIA laboratory director,* may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a laboratory ~~director,~~ *director in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics, or other specialty or subspecialty specified in regulations adopted by the department.*

(b) A person licensed as a clinical laboratory bioanalyst or bioanalyst and qualified under CLIA may perform the duties and responsibilities of a CLIA laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics, or other specialty or subspecialty specified in regulations adopted by the department. ~~A~~

(c) A person licensed as a clinical laboratory bioanalyst or bioanalyst may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

~~SECTION 1.~~

SEC. 2. Section 1204 of the Business and Professions Code is amended to read:

1204. As used in this chapter, "clinical laboratory scientist" means any person, other than a licensed clinical laboratory bioanalyst or trainee, who is licensed under Sections 1261 and 1262 to engage in clinical laboratory practice under the overall operation and administration of a laboratory director, unless serving as a director of a waived laboratory as provided in Section 1209. A person licensed as a clinical laboratory scientist and qualified under CLIA may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and

responsibilities of a waived laboratory director, as specified under CLIA, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics, reproductive biology, or other specialty or subspecialty specified by regulation adopted by the department. A person licensed as a "clinical laboratory scientist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

~~SEC. 2.~~

SEC. 3. Section 1205 of the Business and Professions Code is amended to read:

1205. As used in this chapter, "trainee" means any person licensed under this chapter for the purpose of receiving comprehensive practical experience and instruction in clinical laboratory procedures in one of the sciences or in general clinical laboratory science under the direct and responsible supervision of a person authorized to direct a laboratory under the provisions of this chapter, clinical laboratory scientist, clinical chemist scientist, clinical microbiologist scientist, clinical toxicologist scientist, clinical immunohematologist scientist, clinical genetic molecular biologist scientist, clinical cytogeneticist scientist, clinical biochemical geneticist scientist, clinical reproductive biologist scientist, clinical histocompatibility scientist, or other equivalent licensee in the science or specialty or subspecialty for which he or she is licensed in a clinical laboratory certified for this purpose by the department under this chapter.

~~SEC. 3.~~

SEC. 4. Section 1206 of the Business and Professions Code is amended to read:

1206. (a) For the purposes of this chapter the following definitions are applicable:

(1) "Analyte" means the substance or constituent being measured including, but not limited to, glucose, sodium, or theophyline, or any substance or property whose presence or absence, concentration, activity, intensity, or other characteristics are to be determined.

(2) "Biological specimen" means any material that is derived from the human body.

(3) “Blood electrolyte analysis” means the measurement of electrolytes in a blood specimen by means of ion selective electrodes on instruments specifically designed and manufactured for blood gas and acid-base analysis.

(4) “Blood gas analysis” means a clinical laboratory test or examination that deals with the uptake, transport, and metabolism of oxygen and carbon dioxide in the human body.

(5) “Clinical laboratory test or examination” means the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity, or substance within a biological specimen for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of nondiagnostic tests for assessing the health of an individual.

(6) “Clinical laboratory science” means any of the sciences or scientific disciplines used to perform a clinical laboratory test or examination.

(7) “Clinical laboratory practice” means the application of clinical laboratory sciences or the use of any means that applies the clinical laboratory sciences within or outside of a licensed or registered clinical laboratory. Clinical laboratory practice includes consultation, advisory, and other activities inherent to the profession.

(8) “Clinical laboratory” means any place used, or any establishment or institution organized or operated, for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. That application may include any means that applies the clinical laboratory sciences.

(9) “Direct and constant supervision” means personal observation and critical evaluation of the activity of unlicensed laboratory personnel by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the unlicensed laboratory personnel are engaged in the duties specified in Section 1269.

(10) “Direct and responsible supervision” means both of the following:

(A) Personal observation and critical evaluation of the activity of a trainee by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the trainee is performing clinical laboratory tests or examinations.

(B) Personal review by the physician and surgeon or the licensed person of all results of clinical laboratory testing or examination performed by the trainee for accuracy, reliability, and validity before the results are reported from the laboratory.

(11) "Licensed laboratory" means a clinical laboratory licensed pursuant to paragraph (1) of subdivision (a) of Section 1265.

(12) "Location" means either a street and city address, or a site or place within a street and city address, where any of the clinical laboratory sciences or scientific disciplines are practiced or applied, or where any clinical laboratory tests or examinations are performed.

(13) "Physician office laboratory" means a clinical laboratory that is licensed or registered under Section 1265, and that is either: (A) a clinical laboratory that is owned and operated by a partnership or professional corporation that performs clinical laboratory tests or examinations only for patients of five or fewer physicians and surgeons or podiatrists who are shareholders, partners, or employees of the partnership or professional corporation that owns and operates the clinical laboratory; or (B) a clinical laboratory that is owned and operated by an individual licensed physician and surgeon or a podiatrist, and that performs clinical laboratory tests or examinations only for patients of the physician and surgeon or podiatrist who owns and operates the clinical laboratory.

(14) "Point-of-care laboratory testing device" means a portable laboratory testing instrument to which the following applies:

(A) It is used within the proximity of the patient for whom the test or examination is being conducted.

(B) It is used in accordance with the patient test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory pursuant to paragraph (2) of subdivision (d) of Section 1220.

(C) It meets the following criteria:

(i) Performs clinical laboratory tests or examinations classified as waived or of moderate complexity under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a).

(ii) Performs clinical laboratory tests or examinations on biological specimens that require no preparation after collection.

(iii) Provides clinical laboratory tests or examination results without calculation or discretionary intervention by the testing personnel.

(iv) Performs clinical laboratory tests or examinations without the necessity for testing personnel to perform calibration or maintenance, except resetting pursuant to the manufacturer's instructions or basic cleaning.

(15) "Public health laboratory" means a laboratory that is operated by a city or county in conformity with Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code and the regulations adopted thereunder.

(16) "Registered laboratory" means a clinical laboratory registered pursuant to paragraph (2) of subdivision (a) of Section 1265.

(17) "Specialty" means histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, pathology, genetics, reproductive biology, or other specialty specified by regulation adopted by the department.

(18) "Subspecialty" for purposes of microbiology, means bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other subspecialty specified by regulation adopted by the department; for purposes of diagnostic immunology, means syphilis serology, general immunology, or other subspecialty specified by regulation adopted by the department; for purposes of chemistry, means routine chemistry, clinical microscopy, endocrinology, toxicology, or other subspecialty specified by regulation adopted by the department; for purposes of immunohematology, means ABO/Rh Type and Group, antibody detection for transfusion, antibody detection nontransfusion, antibody identification, compatibility, or other subspecialty specified by regulation adopted by the department; for pathology, means tissue pathology, oral pathology, diagnostic cytology, or other subspecialty specified by regulation adopted by the department; for purposes of genetics, means molecular biology related to the diagnosis of human genetic abnormalities,

cytogenetics, biochemical genetics, or other subspecialty specified by regulation adopted by the department.

(b) Nothing in this chapter shall restrict, limit, or prevent any person licensed to provide health care services under the laws of this state, including, but not limited to, licensed physicians and surgeons and registered nurses, from practicing the profession or occupation for which he or she is licensed.

(c) Nothing in this chapter shall authorize any person to perform or order health care services, or utilize the results of the clinical laboratory test or examination, unless the person is otherwise authorized to provide that care or utilize the results. The inclusion of a person in Section 1206.5 for purposes of performing a clinical laboratory test or examination shall not be interpreted to authorize a person, who is not otherwise authorized, to perform venipuncture, arterial puncture, or skin puncture.

~~SEC. 4.~~

SEC. 5. Section 1207 of the Business and Professions Code is amended to read:

1207. (a) *(1) (A)* As used in this chapter, "clinical chemist," or "clinical microbiologist," or "clinical toxicologist," or "clinical genetic molecular biologist," or "clinical cytogeneticist," or "clinical reproductive biologist," or "clinical biochemical geneticist," or "oral and maxillofacial pathologist" means any person licensed by the department under Section 1264 to engage in, or supervise others engaged in, clinical laboratory practice limited to his or her area of specialization or to direct a clinical laboratory, or portion thereof, limited to his or her area of ~~specialization. Such a licensed person who~~ *specialization.*

(B) A person described in subparagraph (A) may perform the duties and responsibilities of a laboratory director, who is not the CLIA laboratory director, limited to his or her area of specialty or subspecialty as described in subdivision (b), and shall only direct a clinical laboratory providing service within those specialties or subspecialties.

(C) If a person described in subparagraph (A) is qualified under ~~CLIA~~ *CLIA, he or she* may perform clinical laboratory tests or examinations classified as of high complexity under CLIA, and the duties and responsibilities of a *CLIA* laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, limited to his or her

area of specialty or subspecialty as described in subdivision (b), and shall only direct a clinical laboratory providing service within those specialties or subspecialties. ~~A~~

(2) A person licensed as a "clinical chemist," or "clinical microbiologist," or "clinical toxicologist," or "clinical genetic molecular biologist," or "clinical cytogeneticist," or "clinical reproductive biologist," or "clinical biochemical geneticist," or "oral and maxillofacial pathologist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(b) The specialty or subspecialty for each of the limited license categories identified in subdivision (a), and the clinical laboratories that may be directed by persons licensed in each of those categories, are the following:

(1) For a person licensed under this chapter as a clinical chemist, the specialty of chemistry and the subspecialties of routine chemistry, endocrinology, clinical microscopy, toxicology, or other specialty or subspecialty specified by regulation adopted by the department.

(2) For a person licensed under this chapter as a clinical microbiologist, the specialty of microbiology and the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other specialty or subspecialty specified by regulation adopted by the department.

(3) For a person licensed under this chapter as a clinical toxicologist, the subspecialty of toxicology within the specialty of chemistry or other specialty or subspecialty specified by regulation adopted by the department.

(4) For a person licensed under this chapter as a clinical genetic molecular biologist, the subspecialty of molecular biology related to diagnosis of human genetic abnormalities within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(5) For a person licensed under this chapter as a clinical cytogeneticist, the subspecialty of cytogenetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(6) For a person licensed under this chapter as a clinical biochemical geneticist, the subspecialty of biochemical genetics

within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(7) For a person licensed under this chapter as a clinical reproductive biologist, the specialty of reproductive biology or other specialty or subspecialty specified by regulation adopted by the department.

(8) For a person licensed under this chapter as an oral and maxillofacial pathologist, the subspecialty of oral pathology within the specialty of pathology or other specialty or subspecialty specified by regulation adopted by the department.

~~SEC. 5.~~

SEC. 6. Section 1209 of the Business and Professions Code is amended to read:

1209. (a) As used in this chapter, "laboratory director" means any person who is any of the following:

(1) A duly licensed physician and surgeon.

(2) Only for purposes of a clinical laboratory test or examination classified as waived, is any of the following:

(A) A duly licensed clinical laboratory scientist.

(B) A duly licensed limited clinical laboratory scientist.

(C) A duly licensed naturopathic doctor.

(D) A duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (e) of Section 3041.

(3) Licensed to direct a clinical laboratory under this chapter.

(b) (1) A person defined in paragraph (1) or (3) of subdivision (a) who is identified as the CLIA laboratory director of a laboratory that performs clinical laboratory tests classified as moderate or high complexity shall also meet the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory.

(2) As used in this subdivision, "CLIA laboratory director" means the person identified as the laboratory director on the CLIA certificate issued to the laboratory by the federal Centers for Medicare and Medicaid Services (CMS).

(c) The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those

responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

(d) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.

(2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which he or she has been found by the laboratory director to be competent to perform and report.

(e) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.

(f) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

(1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director

shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.

(2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.

(3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.

(g) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:

(A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.

(B) Monitoring the recording and reporting of test results.

(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

(D) Direct observation of performance of instrument maintenance and function checks.

(E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

(F) Assessment of problem solving skills.

(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.

(h) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:

(1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high-quality service.

(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(i) Subdivision (h) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.

(j) A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.

~~SEC. 6.~~

SEC. 7. Section 1210 of the Business and Professions Code is amended to read:

1210. (a) As used in this chapter, "clinical chemist scientist," "clinical microbiologist scientist," "clinical toxicologist scientist,"

"clinical immunohematologist scientist," "clinical genetic molecular biologist scientist," "*clinical biochemical geneticist scientist*," "*clinical reproductive biologist scientist*," "clinical cytogeneticist scientist," and "clinical histocompatibility scientist" means any person, other than a person licensed to direct a clinical laboratory, or licensed as a clinical laboratory scientist or trainee, who is licensed under Sections 1261, 1261.5, and 1262 to engage in clinical laboratory practice. Such a licensed person who is qualified under CLIA may perform clinical laboratory tests classified as of high complexity under CLIA and the duties and responsibilities of a technical consultant, clinical consultant, technical supervisor, and general supervisor limited to the specialty or subspecialty as identified in subdivision (b) for which he or she is licensed by the department. A person licensed as a "clinical chemist scientist," or "clinical microbiologist scientist," or "clinical toxicologist scientist," or "clinical immunohematologist scientist," or "clinical genetic molecular biologist scientist," *or* "*clinical biochemical geneticist scientist*," *or* "*clinical reproductive biologist scientist*," or "clinical cytogeneticist scientist," or a "clinical histocompatibility scientist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(b) The specialties and subspecialties included in each of the license categories identified in subdivision (a), are the following:

(1) For a person licensed under this chapter as a clinical chemist scientist, the specialty of chemistry and the subspecialties of routine chemistry, endocrinology, clinical microscopy, toxicology, or other specialty or subspecialty specified by regulation adopted by the department.

(2) For a person licensed under this chapter as a clinical microbiologist scientist, the specialty of microbiology and the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, virology, or molecular biology and serology for diagnosis of infectious diseases, or other specialty or subspecialty specified by regulation adopted by the department.

(3) For a person licensed under this chapter as a clinical toxicologist scientist, the subspecialty of toxicology within the specialty of chemistry or other specialty or subspecialty specified by regulation adopted by the department.

(4) For a person licensed under this chapter as a clinical genetic molecular biologist scientist, the subspecialty of molecular biology related to the diagnosis of human genetic abnormalities within the specialty of genetics, or other specialty or subspecialty specified by regulation adopted by the department.

(5) For a person licensed under this chapter as a clinical cytogeneticist scientist, the subspecialty of cytogenetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(6) For a person licensed under this chapter as a clinical biochemical geneticist scientist, the subspecialty of biochemical genetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(7) For a person licensed under this chapter as a clinical reproductive biologist scientist, the specialty of reproductive biology, or other specialty or subspecialty specified by regulation adopted by the department.

(8) For a person licensed under this chapter as a clinical immunohematologist scientist, the specialty of immunohematology or other specialty or subspecialty specified by regulation adopted by the department.

(9) For a person licensed under this chapter as a clinical histocompatibility scientist, the specialty of histocompatibility or other specialty or subspecialty specified by regulation adopted by the department.

(c) Clinical chemist scientists, clinical microbiologist scientists, clinical toxicologist scientists, clinical immunohematologist scientists, clinical genetic molecular biologist scientists, clinical cytogeneticist scientists, and clinical histocompatibility scientists shall engage in clinical laboratory practice authorized by their licensure only under the overall operation and administration of a laboratory director.

~~SEC. 7.~~

SEC. 8. Section 1260 of the Business and Professions Code is amended to read:

1260. The department shall issue a clinical laboratory bioanalyst's license to each person who is a lawful holder of a degree of master of arts, master of science, or an equivalent or higher degree as determined by the department with a major in chemical, physical, biological, or clinical laboratory sciences. This

education shall have been obtained in one or more established and reputable institutions maintaining standards equivalent, as determined by the department, to those institutions accredited by the Western Association of Schools and Colleges or an essentially equivalent accrediting agency, as determined by the department. The applicant also shall have a minimum of four years' experience as a clinical laboratory scientist performing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory certified under ~~the~~ CLIA. The quality and variety of this experience shall be satisfactory to the department and shall have been obtained within the six-year period immediately antecedent to admission to the examination. The applicant shall successfully pass a written examination and an oral examination conducted by the department or a committee designated by the department to conduct the examinations, indicating that the applicant is properly qualified. The department may issue a license without conducting a written examination to an applicant who has passed a written examination of a national accrediting board having requirements that are, in the determination of the department, equal to or greater than those required by this chapter and regulations adopted by the department. The department shall establish by regulation the required courses to be included in the college or university training.

~~SEC. 8.~~

SEC. 9. Section 1261.5 of the Business and Professions Code is amended to read:

1261.5. The department may issue limited clinical laboratory scientist's licenses in chemistry, microbiology, toxicology, histocompatibility, immunohematology, reproductive biology, biochemical genetics, genetic molecular biology, cytogenetics, or other areas of laboratory specialty or subspecialty when determined to be necessary by the department in order for licensure categories to keep abreast of changes in laboratory or scientific technology. Whenever the department determines that a new limited clinical laboratory scientist license category is necessary, it shall adopt regulations identifying the category and the areas of specialization included within the category.

To qualify for admission to the examination for a special clinical laboratory scientist's license, an applicant shall have all the following:

(a) Have graduated from a college or university maintaining standards equivalent, as determined by the department, to those institutions accredited by the Western Association of Schools and Colleges or an essentially equivalent accrediting agency with a baccalaureate or higher degree with a major appropriate to the field for which a license is being sought.

(b) Have one year of full-time postgraduate training or experience in the various areas of analysis in the field for which a license is being sought in a laboratory that has a license issued under this chapter or which the department determines is equivalent thereto.

(c) Whenever a limited clinical laboratory scientist's license is established for a specific area of specialization, the department may issue the license without examination to applicants who had met standards of education and training, defined by regulations, prior to the date of the adoption of implementing regulations.

(d) The department shall adopt regulations to implement this section.

~~SEC. 9.~~

SEC. 10. Section 1264 of the Business and Professions Code is amended to read:

1264. The department shall issue a clinical chemist, clinical microbiologist, clinical toxicologist, clinical reproductive biologist, clinical biochemical geneticist, clinical molecular biologist, or clinical cytogeneticist license to each person who has applied for the license on forms provided by the department, who is a lawful holder of a master of science or doctoral degree in the specialty for which the applicant is seeking a license and who has met such additional reasonable qualifications of training, education, and experience as the department may establish by regulations. The department shall issue an oral and maxillofacial pathologist license to every applicant for licensure who has applied for the license on forms provided by the department, who is a registered Diplomate of the American Board of Oral and Maxillofacial Pathology, and who meets any additional and reasonable qualifications of training, education, and experience as the department may establish by regulation.

(a) The graduate education shall have included 30 semester hours of coursework in the applicant's specialty. Applicants possessing only a master of science degree shall have the equivalent

of one year of full-time, directed study or training in procedures and principles involved in the development, ~~modification~~ *modification,* or evaluation of laboratory methods, including training in complex methods applicable to diagnostic laboratory work. Each applicant must have had one year of training in his or her specialty in a clinical laboratory acceptable to the department and three years of experience in his or her specialty in a clinical laboratory, two years of which must have been at a supervisory level. The education shall have been obtained in one or more established and reputable institutions maintaining standards equivalent, as determined by the department, to those institutions accredited by an agency acceptable to the department. The department shall determine by examination that the applicant is properly qualified. Examinations, training, or experience requirements for specialty licenses shall cover only the specialty concerned.

(b) The department may issue licenses without examination to applicants who have passed examinations of other states or national accrediting boards whose requirements are equal to or greater than those required by this chapter and regulations established by the department. The evaluation of other state requirements or requirements of national accrediting boards shall be carried out by the department with the assistance of representatives from the licensed groups. This section shall not apply to persons who have passed an examination by another state or national accrediting board prior to the establishment of requirements that are equal to or exceed those of this chapter or regulations of the department.

(c) The department may issue licenses without examination to applicants who had met standards of education and training, defined by regulations, prior to the date of the adoption of implementing regulations.

(d) The department shall adopt regulations to conform to this section.

~~SEC. 10.~~

SEC. 11. Section 1300 of the Business and Professions Code is amended to read:

1300. The amount of application, registration, and license fees under this chapter shall be as follows:

(a) The application fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's,

clinical microbiologist's, clinical laboratory toxicologist's, clinical reproductive biologist's, clinical biochemical geneticist's, clinical cytogeneticist's, or clinical molecular biologist's license is sixty-three dollars ($63) commencing on July 1, 1983.

(b) The annual renewal fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's, clinical microbiologist's, clinical laboratory toxicologist's, clinical reproductive biologist's, clinical biochemical geneticist's, clinical cytogeneticist's, or clinical molecular biologist's license is sixty-three dollars ($63) commencing on July 1, 1983.

(c) The application fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is thirty-eight dollars ($38) commencing on July 1, 1983.

(d) The application and annual renewal fee for a cytotechnologist's license is fifty dollars ($50) commencing on January 1, 1991.

(e) The annual renewal fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is twenty-five dollars ($25) commencing on July 1, 1983.

(f) A clinical laboratory applying for a license to perform tests or examinations classified as of moderate or of high complexity under CLIA and a clinical laboratory applying for certification under subdivision (c) of Section 1223 shall pay an application fee for that license or certification based on the number of tests it performs or expects to perform in a year, as follows:

(1) Less than 2,001 tests: two hundred seventy dollars ($270).

(2) Between 2,001 and 10,000, inclusive, tests: eight hundred twenty dollars ($820).

(3) Between 10,001 and 25,000, inclusive, tests: one thousand three hundred fifteen dollars ($1,315).

(4) Between 25,001 and 50,000, inclusive, tests: one thousand five hundred eighty dollars ($1,580).

(5) Between 50,001 and 75,000, inclusive, tests: one thousand nine hundred sixty dollars ($1,960).

(6) Between 75,001 and 100,000, inclusive, tests: two thousand three hundred forty dollars ($2,340).

(7) Between 100,001 and 500,000, inclusive, tests: two thousand seven hundred forty dollars ($2,740).

(8) Between 500,001 and 1,000,000, inclusive, tests: four thousand nine hundred ten dollars ($4,910).

(9) More than 1,000,000 tests: five thousand two hundred sixty dollars ($5,260) plus three hundred fifty dollars ($350) for every 500,000 tests over 1,000,000, up to a maximum of 15,000,000 tests.

(g) A clinical laboratory performing tests or examinations classified as of moderate or of high complexity under CLIA and a clinical laboratory with a certificate issued under subdivision (c) of Section 1223 shall pay an annual renewal fee based on the number of tests it performed in the preceding calendar year, as follows:

(1) Less than 2,001 tests: one hundred seventy dollars ($170).

(2) Between 2,001 and 10,000, inclusive, tests: seven hundred twenty dollars ($720).

(3) Between 10,001 and 25,000, inclusive, tests: one thousand one hundred fifteen dollars ($1,115).

(4) Between 25,001 and 50,000, inclusive, tests: one thousand three hundred eighty dollars ($1,380).

(5) Between 50,001 and 75,000, inclusive, tests: one thousand seven hundred sixty dollars ($1,760).

(6) Between 75,001 and 100,000, inclusive, tests: two thousand forty dollars ($2,040).

(7) Between 100,001 and 500,000, inclusive, tests: two thousand four hundred forty dollars ($2,440).

(8) Between 500,001 and 1,000,000, inclusive, tests: four thousand six hundred ten dollars ($4,610).

(9) More than 1,000,000 tests per year: four thousand nine hundred sixty dollars ($4,960) plus three hundred fifty dollars ($350) for every 500,000 tests over 1,000,000, up to a maximum of 15,000,000 tests.

(h) The application fee for a trainee's license is thirteen dollars ($13) commencing on July 1, 1983.

(i) The annual renewal fee for a trainee's license is eight dollars ($8) commencing on July 1, 1983.

(j) The application fee for a duplicate license is five dollars ($5) commencing on July 1, 1983.

(k) The personnel licensing delinquency fee is equal to the annual renewal fee.

(*l*) The director may establish a fee for examinations required under this chapter. The fee shall not exceed the total cost to the department in conducting the examination.

(m) A clinical laboratory subject to registration under paragraph (2) of subdivision (a) of Section 1265 and performing only those clinical laboratory tests or examinations considered waived under CLIA shall pay an annual fee of one hundred dollars ($100). A clinical laboratory subject to registration under paragraph (2) of subdivision (a) of Section 1265 and performing only provider-performed microscopy, as defined under CLIA, shall pay an annual fee of one hundred fifty dollars ($150). A clinical laboratory performing both waived and provider-performed microscopy shall pay an annual registration fee of one hundred fifty dollars ($150).

(n) The costs of the department in conducting a complaint investigation, imposing sanctions, or conducting a hearing under this chapter shall be paid by the clinical laboratory. The fee shall be no greater than the fee the laboratory would pay under CLIA for the same type of activities and shall not be payable if the clinical laboratory would not be required to pay those fees under CLIA.

(o) The state, a district, city, county, city and county, or other political subdivision, or any public officer or body shall be subject to the payment of fees established pursuant to this chapter or regulations adopted thereunder.

(p) In addition to the payment of registration or licensure fees, a clinical laboratory located outside the State of California shall reimburse the department for travel and per diem to perform any necessary onsite inspections at the clinical laboratory in order to ensure compliance with this chapter.

(q) The department shall establish an application fee and a renewal fee for a medical laboratory technician license, the total fees collected not to exceed the costs of the department for the implementation and operation of the program licensing and regulating medical laboratory technicians pursuant to Section 1260.3.

(r) The costs of the department to conduct any reinspections to ensure compliance of a laboratory applying for initial licensure shall be paid by the laboratory. This additional cost for each visit shall be equal to the initial application fee and shall be paid by the laboratory prior to issuance of a license. The department shall not charge a reinspection fee if the reinspection is due to error or omission on the part of the department.

(s) A fee of twenty-five dollars ($25) shall be assessed for approval of each additional location authorized by paragraph (2) of subdivision (d) of Section 1265.

(t) On or before July 1, 2013, the department shall report to the Legislature during the annual legislative budget hearing process the extent to which the state oversight program meets or exceeds federal oversight standards and the extent to which the federal Department of Health and Human Services is accepting exemption applications and the potential cost to the state for an exemption.

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